REMARKS

The application has been amended and is believed to be in condition for allowance.

In the claims, the term "elliptical" has been amended to --approximately elliptical-- to ensure the claims read on shapes that are not perfectly elliptical.

The claims have been amended to remedy the stated basis of rejection under section 112, second paragraph. Withdrawal of this rejection is therefore solicited.

Claim 14 and new claims 16-17 recite the cap (3), removed from body, is configured to have the lugs co-operate with the ribs to lock the cap on the lancet.

Claims 18-20 recite wherein, removal of the cap automatically removes the lancet, the co-operation of the lugs and ribs performing a capture, an extraction, and a locking as the cap is pulled off the firing device. See that the claims are each somewhat different.

Claims 12 and 21-22 recite wherein, a portion of the exterior surface of the cap extending to the rear of the cap being a continuous wall.

Claims 8-15 were rejected as obvious over STRONG et al. 5,324,303 in view of ITOH 3,651,972.

The claims now more specifically recite the invention. See, e.g., claim 8 which recites two axially spaced ribs (7, 8) located on the body and defining a gap therebetween. There is

also recited two inwardly-directed opposed lugs (14), limited in position to an internal part of the constant approximately elliptical cross-section portion (13), the two inwardly-directed opposed lugs (14) located on an inner surface of the constant approximately elliptical cross-section portion (13) on the minor axis thereof.

Further claim 8 recites that upon firing the lancet the needle tip momentarily projects through the aperture and then retracts so that the needle tip is within the cap and the opposed lugs are proximate the gap between the two ribs.

Such a structure is neither taught nor suggested by the prior art.

Further, the claims not merely recite a differently shaped cap (i.e., an elliptical cap) but rather recite a specific structure which functions in a manner not found in the prior art.

The recited axially spaced ribs are abutments (see claim 10) and provide an important safety feature (now recited more clearly). See that claim 8 requires a structure that "upon removal of the firing device from the cap, the constant approximately elliptical cross-section portion (13) resumes the approximately elliptical cross-section with the opposed lugs (14) closing towards each other and engaging the gap between the two ribs to capture the ribs and to capture the body within the cap".

Without this structure (rearward abutment 8), there is a risk that the cap moves too far rearwardly relative to the

lancet body thus re-exposing the needle through the aperture and thus leading to possible injury.

Further, the cap (3) is configured to have the lugs co-operate with the ribs to lock the cap on the lancet (when the cap is removed).

Unlike the applied art, the invention provides a structure wherein, the lugs 14 and the resiliently deformable nature of the cap are designed so that, as the cap is slid off the firing device the lugs 14 spring back into grip in the gap between the ribs 7, 8 so that pulling the cap off automatically ensures removal of the lancet. The co-operation between the lugs 14 and ribs 7, 8 therefore demands that there be capture, extraction and locking, as the cap is pulled off the firing device.

By contrast, in STRONG, as explained in the passage in column 9, line 62 to column 13, line 8, the multi-function cap is ejected not by pulling it off manually but by means of a sequential ejection operation utilizing the ejector pins and an ejector sleeve 71. As explained in the quoted passage, the lancet is first pushed further into the cap by means of the ejector pins 75 inside the device and thereafter a cylindrical ejection sleeve 71 dislodges the locking legs of the cap to eject both the lancet and the cap. In other words, the lancet is initially pushed forwards whereafter the cap is pushed forwards to remove it from the end of the body of the device. Thus, in

this document, there is no suggestion of an arrangement in which pulling away of the firing device from the cap causes the cap to lock about the lancet. The groove 25 in STRONG therefore simply performs the function of locking when the lancet has been pushed out and the cap has been pushed off the end of the device and is not designed to be captured by lugs on the cap as the cap is pulled off the device. There is no disclosure of the spaced rib structure such as would be necessary to effect removal by a pulling operation. Furthermore, the sequential movement required of the lancet followed by the cap means that the legs of the cap are not proximate to the shallow groove 25 in the lancet after firing.

Further, the present rejection appears to be based on hindsight.

The Official Action is applying a hefty dose of hindsight in reaching out to combine the lancet technology of STRONG with the snap-fit cap of ITOH.

ITOH is concerned with a cap or closure for a container which can be snapped onto and off the container without requiring the conventional rotational engagement. There is no secondary function performed by the cap; its only purpose is to serve as a closure element and it does not coact with any other structure other than the neck portion of the bottle or other container.

STRONG discloses a combined lancet and multi-function cap in which the cap fulfills multiple functions (see column 2,

lines 17-60). It serves as a protective cap to keep the sharp needle protected and sterile; it acts as an isolation cap/physical intermediary to bear against the skin during the lancing operation so that only the cap makes physical contact with the patient's skin. The cap also serves to control the depth of penetration. The cap serves as a protective cap or locking hood to cap and permanently lock the lancet needle after use. The cap also serves to prevent the lancet from being fired accidentally for a second time.

There are numerous physical differences between the combined lancet and multi-function cap disclosed in STRONG and that claimed:

• The claim requires that the cap has an exterior surface which flares outwardly from the base into an elliptical cross-section at a break circumference. There is no outward flaring in the cap of STRONG.

• The claim requires the exterior surface to extend beyond the break circumference at a constant elliptical cross-section portion. This inherently requires that the portion extending to the rear of the cap is a continuous wall. In STRONG the disclosed structure is four equispaced fingers tapering inwardly.

• There is no way in which the cap of STRONG could be squeezed at opposite points to cause it to deform into a circular cross-section.

• The cap of STRONG does not resume an elliptical cross-section to capture the lancet body within the cap.

A further observation is that the cap of STRONG would not work if the spaced, inwardly tapering fingers were replaced by a continuous, constant, elliptical section. It is a requirement of the arrangement of STRONG that the cap is removed by a cylindrical ejector shell 71 whose forward end contacts the locking ends 21 on the legs of the cap to remove them from the groove 57. For this action to work, the radial arms need to be capable of simultaneous outward flexing. Replacing fingers with a continuous wall would be a strange step to take because it would be obvious to one skilled in the art that the resistance to hoop stresses provided by a continuous wall are so much greater than the resistance to movement of four independently flexible fingers, and that the device would not operate as required.

The claimed invention also has advantages over STRONG because of the continuous wall shrouds access to the lancet and furthermore provides a more secure attachment which is less likely to be susceptible to inadvertent removal by being knocked off. This arrangement is not taught by the prior art.

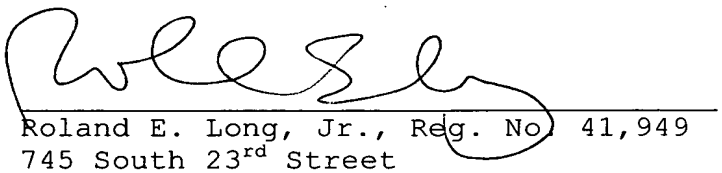
For all these reasons, the claims are believed non-obvious.

Accordingly, reconsideration and allowance of the pending claims are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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